

REMARKS

Applicant respectfully requests reconsideration. Claims 45, 46, 48, 51-53 and 72-102 were previously pending in this application. Claim 45 has been amended. Claims 45, 46, 48, 51-53 and 72-102 remain pending in this application. No new matter has been added.

Rejections Under 35 U.S.C. §112

Claims 45, 46, 48, 51-53 and 72-102 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. Specifically, the Office Action asserts that the preamble of the claims are indefinite because the claims fail to describe what type of method is being performed, and that it is unclear whether the claims are drawn to a method of accumulating an opaque material or whether the claims are drawn to a method of detection of a sample component that binds with a binding partner disposed on the substrate. The Office Action also states that the claims lack correlation because the purpose of the recited method steps is not described in the preamble of the claim.

Applicant notes that what is required under 35 U.S.C. §112, second paragraph, is that those skilled in the art understand what is being claimed when the claims are read in light of the specification. Orthokinetics v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1 USPQ 2d 1081 (Fed. Cir. 1986). In the present case, the limitations recited in claim 45, when read in light of Applicant's specification and figures, would be clearly understood by those of ordinary skill in the art. However, without conceding to the correctness of the rejection and solely to advance the patent application process, Applicant has amended the preamble of independent claim 45 to recite "A method of determining a sample component". The step of "determining the sample component" has also been added to independent claim 45. It is believed that the rejections on the present grounds have been overcome, and reconsideration is respectfully requested.

Claims 45, 46, 48, 51-53 and 72-102 are rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the

steps. Specifically, the Office Action states that the omitted steps are: associating a metal colloid with the sample component-binding partner complex and detection of the opaque material to assay for the sample component. Applicant respectfully traverses.

As an initial matter, Applicant notes that a rejection, such as the present one asserting that a claim lacks an essential step or limitation, is properly made under 35 U.S.C. 112, first paragraph for lack of enablement (MPEP §2172.01). Therefore, the basis of the present rejection is believed to be improper.

Moreover, it is well established that a claim will fail as being non-enabled only if it omits matter *disclosed to be essential* to the invention as described in the specification or in other statements of record. (MPEP §2172.01, emphasis added; see also MPEP §2164.08¹). Nowhere are the steps of associating a metal colloid with the sample component-binding partner complex and detection of the opaque material to assay for the sample component disclosed or suggested in Applicant's specification as being essential to the invention. Accordingly, even presuming that 35 U.S.C. §112, second paragraph is a proper basis for the rejection, which it is not for at least the reasons noted above, the rejection cannot be maintained.

The Office Action also asserts that the claims are indefinite because the opaque material has no purpose without the presence of a metal colloid associated with the sample component-binding partner complex, and that a detection step cannot be performed without the presence of a metal colloid. Applicant respectfully disagrees. In making these determinations, the Office Action points to several paragraphs from the present application where the use of a metal colloid is described. Applicant notes, however, that these teachings are merely examples of how an opaque layer may be formed, and that the scope of the claims is not limited by such teachings. For instance, Applicant's

¹ "A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such claim under the enablement provision section of 35 U.S.C. §112. See *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976). In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567 (CCPA 1976).

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made *only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended*. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality." (Quoting MPEP §2164.08, emphasis added).

specification at page 5, lines 5-6 states, “Any antigen-antibody complex that forms may be associated with a metal colloid that provides a catalytic surface for the deposition of an opaque material, such as a layer of metal”. (Emphasis added.) This language is clearly permissive and does not require any antigen-antibody complex that forms to be associated with a metal colloid. Additionally, Applicant’s specification teaches that a metal layer (which may involve the use of a metal colloid associated with a sample component-binding partner complex) is but one example of an opaque layer, as opaque layers can also include polymeric layers. See page 5, lines 22-23. Certainly, one of ordinary skill in the art would understand that the formation of opaque layers in the form of polymeric layers do not necessarily require the presence of a metal colloid.

It appears that the Patent Office’s basis for objection to claim 45 may be it believes that the claim reads broader than certain specific, exemplary compositions in Applicant’s specification. However, claim breadth is not an appropriate basis for a rejection under 35 U.S.C. §112, second paragraph, so long as those of ordinary skill in the art would understand the scope of the claim in view of the specification. MPEP §2173.04; In re Miller, 441 F.2d 689 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, as in the present case, and if the Applicant has not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. §112, second paragraph.

Relevant to this rejection, Applicant also points out that the law does not require that claims be limited by the specific compositions or examples mentioned in Applicant’s specification, so long as the claims are properly enabled by the specification. Claims can be, and typically are, broad enough to cover at least some embodiments not specifically exemplified in the specification. Indeed, “[t]o demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for ‘preferred’ materials in a process... would not serve the constitutional purpose of promoting progress in the useful arts.” In re Goffe, 542 F.2d 564, 567 (CCPA 1976).

Applicant believes that claim 45 is definite and clear to those of ordinary skill in the art and, therefore, is in full compliance with 35 U.S.C. §112, second paragraph. The remaining claims depend from claim 45, and, thus, are also in full compliance with 35 U.S.C. §112, second paragraph.

Accordingly, Applicant respectfully requests withdrawal of the claim rejections on these grounds.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 23/2825 under Docket No. H0498.70211US02 from which the undersigned is authorized to draw.

Dated: 11/3/09

Respectfully submitted,

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